

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application

Serial No. 10/707,921

Applicant: ERFAN, Onjé

Filed 01/26/2004

TC/AU 3762

Examiner: Lenwood Faulcon Jr.

Attorney Docket No. ERF125

Customer No. 26092

Confirmation No. 1920

**DECLARATION OF ONJÉ ERFAN, M.D.
UNDER 37 C.F.R. 1.132**

1. I am Dr. Onjé Erfan, a medical doctor. I am also applicant and inventor in U.S. patent application serial no. 10/707,921.
2. I studied auricular medicine under Dr. Paul F.M. Nogier, known as the father of auricular medicine. Dr. Nogier performed pioneering works in this area and was well known throughout the world for his identification of ear points that correlated with certain symptoms and diseases. Dr. Nogier's publications include:
Nogier, Paul FM. *From Auriculotherapy to Auriculomedicine*. Maisonneuve, 1983.
Nogier, Paul FM. *Handbook of Auriculotherapy*. Maisonneuve, 1981.
3. In addition to studying directly under Dr. Nogier, I have specialized in auricular medicine in my professional practice. I have consulted with other leading practitioners in this specialty. I am also familiar with the work of Dr. Kim, who is the first-named applicant in U.S. Patent 5,514,175, which is a background patent of record in the examination of the present application.
4. My patent application is directed to a specific goal that does not appear in patents or literature known to me or of record in the background patents of this patent application. The goal is to enable substantially any patient to obtain a ready-made, standard headset that will allow him to consistently, safely and effectively treat himself via the bilateral headset, using trans-cranial stimulation via Arnold's branch of the Vagus nerve.

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5. In the recent background patents in the name of Kim and both patents to McCall clearly indicate that each earpiece must be custom to each patient, often by the initial step of forming a cast of the ear so as to then match a custom-made earpiece. The points to be stimulated must be custom located on the live ear. The electrodes must be custom located in the custom earpiece so as to strike those points. These patents clearly do not enable achievement of my goal.

6. I note these several patents would locate and stimulate acupuncture points, which may be distinguished from Arnold's branch of the Vagus nerve. My headset is designed to reliably locate and contact Arnold's branch of the Vagus nerve in the conch of the human ear. Clinical trials confirm the efficacy of this mode of treatment. I know of no other anatomical location where the Vagus nerve can be contacted non-invasively. The mounting and pivoting of the earpieces is suited to contact Arnold's branch of the Vagus nerve and not to enter the ear canal. The electrical stimulation is suited for application to Arnold's branch of the Vagus nerve, for trans-cranial stimulation. These characteristics distinguish the configuration and operation of my headset from devices directed to other forms of treatment.

7. According to my understanding, the background patent to Colsen describes a sheet electrode that plugs into the ear hole or external auditory canal so as to make blanket contact with the surrounding tissues. In order to complete a circuit, a grounding clip is clipped to the ear helix. Then a high voltage is applied between the sheet electrode and grounding clip. The claimed result is creation of an electrified zone between the poles, covering a substantial surface area of the ear between the poles, and stimulating any points that fall in the zone.

8. In my opinion, the treatment described in the Colsen patent is not consistent, safe, and effective for the patient to practice upon himself. One reason is that the creating a broad electrified zone across an expanse of tissue, large enough in size so as to require application of high voltage, can be dangerous or lead to harmful results.

9. I am aware of non-published clinical reports of cardiac irregularities with application of strong electrical stimulation to the ear canal; and in pregnant females, possibility of spontaneous abortion. I see nothing in the description of the broad blanket electrode and variably applied ground electrode in the Colsen device that provides suitable safety over improper use or improper placement, such a might lead to a harmful event.

10. I note that the background patent to Leech describes stimulation of the auditory nerve, to restore hearing, via a circuit extends from the ear to the neck or hand. The background patent to Pollard describes a headset designed for insertion of electrodes into

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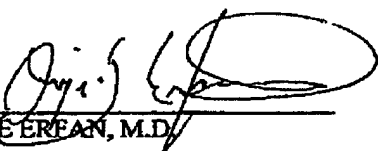
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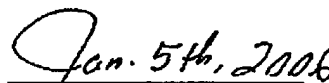
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the ears to discharge electricity between them. The background patent to Faltys describes a surgical implant of a tissue stimulator. In my opinion, any relationship to my headset is tenuous.

VERIFICATION:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any document or any patent resulting there from.


ONJE ERFAN, M.D.


Date